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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,472

04/06/2005

Jeremy Marshall

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,472	<b>Applicant(s)</b> MARSHALL ET AL.	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/9/2008 has been entered.

### ***Acknowledgements***

2. This office action is in response to the reply filed on 1/9/2008.
3. In the reply, the Applicant cancelled claims 1-4, 7-8 and added new claims 9-13
4. Thus, claims 9-13 are pending for examination.

### ***Claim Objections***

5. Claim 9 objected to because of the following informalities: Claims 9 recites "forwards" in In 16, the Examiner believes the limitation should read "forward".  
Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claim 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recited the limitations "the second spring

meanwhile serving to retain the syringe seated at its forward position, whereby said piston is not acted upon until the needle has penetrated.” The Examiner is still unclear as to the recitation of this limitation in relation to the metes and bounds of claim 9.

8. It appears that the Applicant is intending to recite that the second spring functions to retain the syringe seated at its forward position, or the extended position wherein the needle is penetrating the skin. However, as claimed in claim 9, the second spring acts in opposition to the first spring that applies the force necessary to move the needle into the extended position to pierce the skin and perform the injection. The force and function of the second spring, as claimed in claim 1, appears to be in opposition to retaining the syringe seated at its forward position. Furthermore, the second spring cannot act to retain the syringe in a forward position where the needle is exposed because the second spring is located between the plunger and the syringe. The spring does not contact the housing in any manner and cannot act in any manner to control the positioning of the syringe in the housing.

9. Furthermore, “whereby said piston is not acted upon until the needle has penetrated” is additionally indefinite. The Examiner is unsure the recited element being claim that is not acting upon the piston. Is it the first spring? Second spring? Plunger? Furthermore, the term “acted upon” is indefinite because acted upon is broad enough to include, for instance, the scope of ‘in contact with’. The piston is always in contact with the plunger and therefore is always being acted upon by the plunger. The Examiner suggests clarifying the way, ie – forcibly moved, the action upon the piston occurs or results.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**11.** Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergens et al (6270479). An injection device (Figs 1A-D) comprising: a housing (Figs 1A-D) having a forward end and a rearward end; a syringe (120) having a needle (123) and containing a dose (120; Figs 1A-D) for being ejected through said needle by means of a piston (125) slideable within the syringe, said syringe being moveable within the housing to a forward position to project its needle (Figs 1b-1c) from the forward end of the housing; a spring drive operable firstly to urge the syringe to its forward position and then to press said piston to eject said dose (Figs 1A-D), said drive including: a first spring (141) acting between the housing and a plunger (126) aligned to cooperate with the piston (126) to urge the piston forwardly, and a second spring (156) acting in compression (col 12, lns 46-50, col 13 lns 2-6; Figs 1A-D) between said plunger and the syringe and in opposition to said first spring when the plunger presses said piston forwards to eject the dose (col 12, lns 7-col 13, lns 19), the second spring being weaker than the first spring but being sufficiently stiff to be in an expanded state when the syringe reaches its forward position with its needle penetrating the flesh of a patient (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9), whereupon the first spring, as it fully expands, will then compress the second spring to urge the plunger forward and thereby

move the piston and expel a dose from the syringe (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9); further comprising a third, light spring (134) urging the syringe rearwardly so that its needle is retracted within the housing prior to use (Fig 1A); wherein the ejection of said dose is caused by further expansion of said first spring and is accompanied by compression of said second spring throughout the stroke of movement of said piston (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9); wherein during initial expansion movement of said first spring, said piston is isolated from the thrust of said first spring solely by the opposing force of the second spring (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9; Figs 1A-D; wherein upon initial release of 1<sup>st</sup> spring 141 the syringe moves forwards (Figs 1—1B) compressing 3<sup>rd</sup> spring 134); wherein the first spring contacts the plunger and the housing and the second spring contacts the plunger and the syringe (Figs 1a-d; col 12 and 13; wherein the scope of the term 'contacts' includes 'in association' or 'in connection' or 'in interaction'). Also, see discussion below in Response to Arguments.

### ***Response to Arguments***

12. Applicant's arguments filed 1/9/2008 have been fully considered but they are not persuasive.

13. The Applicant argues:

- i. Bergens et al is impossible to one of ordinary skill in the art to determine how Bergens et al operates (Remarks, pg 4, paragraph 6)

- ii. The spring 156 does not act in opposition to the 1st spring when the plunger presses the piston forward to eject the dose because the action of the spring 156 is decoupled from the drive plunger before the drive plunger presses the syringe plunger (Remarks, pg 5, paragraph 3-pg 6, paragraph 1)

14. In response to applicant's argument (i), the Examiner notes that Bergens et al is an issued US patent and has thus met all requirements to one of ordinary skill in the art for disclosure and enablement pursuant to 35 USC 101 and 112. Secondly, the Examiner has discussed the reference in-depth on the record and finds no confusion in the operation of Bergens et al. Lastly, the possible modes of operation discussed in the Remarks by the Applicant are purely speculative in nature and ignore the disclosure and description present in Bergens et al.

15. In response to applicant's argument (ii), the Examiner notes that Bergens et al explicitly discloses:

16. The damper can be arranged for energy absorption from the autopenetration movement, for which purpose the damper should yield under a pressure weaker than the force provided by the autopenetration drive but preferably be stronger than force provided by the autoreturn mechanism when present. (col 9, lns 23-28)

17. Most preferably a damper is arranged for energy absorption from the autoinjection movement, for which purpose the damper

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should yield under a pressure weaker than the force provided by the autoinjection drive. (col 9, lns 62-67)

18. During autoinjection, however, it is preferred that a damper is additionally or alternatively provided for the purpose of controlling injection movement speed and force in order to make the autoinjection phase usable for a broad range of forces with maintained uniform movements speeds, as described in the introduction. (col 10, lns 3-9)

19. As indicated the damper should preferably be arranged to be active during the actual injection stroke as well as during any further initial length necessary for allowing the injection head to start from a for all container types contemplated common start position for the injection phase. (col 10, lns 30-36)

20. The latter can be accomplished if the damper is connected between the autopenetration head and the autoinjection head, whereby damper movement will only take place when the injection head moves relative the penetration head, normally after completed penetration. (col 10, lns 40-46)

21. A common drive system includes a spring 141 acting as both as penetration drive and injection drive. (col 12, lns 14-16)

22. Between the syringe plunger 151 and the plunger guide 153 a compression damper spring 156 is arranged in slots, biasing the



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plunger guide 153 towards a rear position relative the syringe plunger 151. (col 12, lns 29-33)

23. The tapering surfaces become active for compression of the legs when the plunger guide moves forward relative the syringe plunger against the force of the damper spring, which is weaker than the drive spring 141. (col 12, lns 46-50)

24. The drive spring 141 is compressed. The container 120 is pressed to a rear needle-hidden position by return spring 134. In FIG. 1B a trigger (not shown) has been released and drive spring 141 has acted on injection head 142, which in turn has acted on plunger guide 153 to move syringe plunger 151, into contact with container barrel or fingergrasp 124, thereby moving the container and carrier 130 into a needle-exposed position. At the end of this penetration movement the container and carrier have stopped together with syringe plunger 151 but the plunger guide 153 has continued its forward movement against the weaker force of damping spring 156, the relative movement between which parts has made the tapering surface 161 cause a compression of legs 143 and the injection head has landed on container plunger 126. (col 13, lns 63-col 13, lns 8).

25. Additionally, see citations cited above in rejection.

26. Bergens et al explicitly discloses that the second spring (156) acts in direct opposition - ie dampening - to the first spring during the penetration stage after the needle has finished the penetration stage and has penetrated the skin of the patient.

27. The Examiner notes that after the conclusion of the penetration stage, the legs (143) move into expansion cavity (163) at a position that corresponds to the plunger's final position in the empty syringe (col 12, lns 50-58; Fig 1D), and this allows the needle and syringe to be retracted under the force of the 3rd return spring (134).

28. The rejection is maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767